

We hope this issue of the *BMJ* will stimulate similar initiatives, promoting a dialogue about health throughout the region.

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Competing interests: None declared.

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## Marketing of medicines in India

### *Informing, influencing, or inducing?*

India has a large pharmaceutical industry. A major expansion started in the early 1970s when the Indian government took two fateful decisions. Firstly, it decided to permit domestic manufacturers to produce generic versions of patented molecules without permission from overseas innovators—provided a different manufacturing process was employed. Secondly, small scale pharmaceutical units were eligible for huge fiscal incentives and state subsidies. The new policy led to an unprecedented growth of medicine makers. Today an estimated 17 000 pharmaceutical companies produce over 40 000 branded formulations, many times more than the rest of the world.

Since the industry has free access to medicines discovered abroad, there is little incentive to undertake research to make new drugs. Consequently, nearly all companies are engaged in vicious competition to sell the same molecules under different brand names. Over 140 brands of omeprazole and over 120 brands of cefadroxil exist in India. As companies resort to unconventional methods to sell their brands, ethics take a back seat. Expanding indications, exaggerating efficacy, ignoring contraindications, and underplaying adverse effects have become routine practice.

Some recent examples illustrate these questionable marketing methods. Nimesulide, a non-steroidal anti-inflammatory drug, is being recommended for use in neonates and infants for undiagnosed fever. The European Medicine Evaluation Agency has contraindicated its use in children below 12 years due to its hepatotoxic potential.<sup>1</sup> Metoclopramide is marketed for nausea and vomiting in all age groups including low birthweight neonates,<sup>2</sup> though its use was restricted in the West in the mid-1990s to people aged over 18 years. The Nootropil brand of piracetam is indicated for cortical myoclonus in people older than 16 years.<sup>3</sup> In India, it is recommended for social maladjustment, lack of alertness, loss of memory, and learning disabilities in children. Known side effects are conveniently side stepped.

Companies find it hard to generate prescriptions based solely on science. Relying on published datasheets issued by the inventing companies reduces the scope of a drug because of the inconvenience of contraindications, precautions, drug interactions, and adverse effects. Sometimes, for purely promotional purposes local data are generated, as happened with letrozole, which was given to over 430 young women to test its efficacy in inducing ovulation.<sup>4</sup>

Without new molecules, companies create "novel" products by mixing two or more medicines in a fixed dose combination. Such combinations are often irrational, and some pose danger. Short term use of combinations of quinolones with imidazoles for undiagnosed diarrhoea is encouraging *Salmonella typhi* resistance to quinolones.<sup>5</sup>

Just as elsewhere, gifts and other incentives to prescribers are used by manufacturers to promote their products—and the methods are often ingenious. There is little consumer resistance to these practices for two reasons: faith in the perceived integrity of the medical profession, and lack of information. An examination of 1200 randomly selected formulations showed that only 316 had package inserts, and none had patient information leaflets.<sup>6</sup> Many poor, illiterate people in India ask pharmacists for medicines for common problems such as colds, cough, aches, and pains. In order to tap this lucrative market, companies produce "branded generics." These are not promoted to the medical profession, but to pharmacies, which are offered huge discounts. In the process it is conveniently forgotten that inducing pharmacies to sell prescription drugs without prescriptions is unethical and illegal.

The commercial needs of countless, fiercely competing pharmaceutical companies have led them to depend on the tried and tested 3Cs: convince if possible, confuse if necessary, and corrupt if nothing else works. It is easy to find fault with policies adopted decades ago, and the fault may lie in the regulatory system failing to keep pace with innovations in the pharmaceutical industry.

*BMJ* 2004;328:778-9

Nevertheless, the government has failed in its duty of preventing unethical promotion that has already resulted in misery, illness, and death.

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Competing interests: None declared.

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## Postgraduate medical education in South Asia

*Time to move on from the postcolonial era*

Undergraduate and postgraduate education increased rapidly in the post-independence era in South Asia—except for Bhutan and the Maldives, which do not have medical schools. Now in India alone, 136 medical schools admit more than 6000 trainees into postgraduate programmes.<sup>1</sup>

Satisfaction over the numbers who have completed postgraduate education conceals the challenges facing the region. Specialist training is in the traditional apprenticeship style rather than an appraisal based approach. Selection of assessment tools is not governed by modern educational theory. Some postgraduate examinations rely on outmoded assessments, such as essays and long cases. Training in research, ethical issues, concepts of team work, and management is variable. Standards for accreditation are ill defined and not uniformly applied. Training programmes are rarely subjected to external review or internal quality control. National medical councils, expected to set and maintain standards, have failed to introduce quality assurance measures on a par with the UK's General Medical Council or the Liaison Commission on Medical Education in the United States.

Some countries and institutes, however, have initiatives to meet these challenges. The Postgraduate Institute of Medicine of Sri Lanka and the College of Physicians and Surgeons of Pakistan invite external examiners for their final examinations, mostly from UK royal colleges but also from Australia, India, Singapore, and New Zealand. External examiners also review study programmes, and provide training to local educators. Trainees at the specialist registrar level at the Sri Lankan institute must complete a year of training in an approved centre in the United Kingdom, Australia, New Zealand or Singapore. These measures have helped challenge and maintain standards. In Bangladesh all postgraduate courses at state medical schools are subject to quality control.

India is reaping the benefits of the foresight of leaders such as Pundit Jawaharlal Nehru, who made considerable investments in developing science and technology—after independence—albeit from a meagre budget. Subsequent government policies have ensured that India is studded with centrally supported—and regulated—institutes of postgraduate excellence in medicine, science, and information technology. Bangladesh, India, and Pakistan also boast numerous centres of excellence devoted to single specialties such as cardiovascular disease, endocrinology, ophthalmology,

neuroscience, and mental health. What is missing is a system of accreditation for these centres.

In most countries in South Asia, professional colleges and associations supervise a variety of continuing medical education programmes but there is no revalidation process and no system of awarding credits for educational activities. The College of Physicians and Surgeons Pakistan has initiated a dialogue among stakeholders, however, to introduce revalidation, and the Medical Council of India awards grants for such activities.<sup>2</sup> The Sri Lankan experience is that revalidation is not acceptable to all stakeholders. A plan has emerged to set up a national council and district committees for continuing professional development by January 2005, and a detailed points scheme is being drawn up.<sup>3,4</sup>

Every country in the region has a core of medical academics and specialists with a vision of a better system. A region wide group devoted to improving postgraduate education could drive quality improvement. Professional colleges and associations in the region can play an important part through advocacy and raising debate and awareness about issues relating to postgraduate education. And lastly, policy makers at the highest level such as government ministers must be lobbied to encourage policies that will drive change. Otherwise, any optimism about medical education in the region will remain unfulfilled.

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Competing interests: None declared.

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